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EXAMINER

MITCHELL, TEENA KAY

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 16, 21-27, 32, 34-38, and 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (3,912,795) in view of Ko ('527)**

Jackson in a humidification system discloses a supply unit (Fig. 1; 28, , 22, 24, 18) **configured to** deliver humidified gas (via 18; Col. 2, lines 42-67); a delivery tube assembly (at 10) having a delivery tube (Fig. 1, via (10)) with a proximal end and a distal end, said delivery tube assembly also having a fitting positioned at said proximate end (at 12) of said delivery tube and releasably coupled to said supply unit (Fig. 1), said delivery tube assembly being **configured to** transfer heat to the humidified gas received from said supply unit (Fig. 1). The difference between Jackson and claim 16 is a nasal cannula releasably coupled to the distal end of the delivery tube to receive humidified gas from the delivery tube of the delivery tube assembly. Ko. (Col. 10, lines 29-31) teaches a releasable nasal cannula (148) or an endotracheal tube to a connector member (146) of a gas delivery tube providing a means for releasably connecting a

plurality of different patient interfaces to a gas delivery conduit. It would have been obvious to substitute the respiratory device of Jackson with a nasal cannula because it would have provided a means for releasably connecting a plurality of different patient interfaces to a gas delivery device as taught by Ko, therefore the substitution of a nasal cannula for the respiratory delivery device of Jackson would have been obvious to one of ordinary skill in the art one respiratory delivery device for another.

Regarding claim 20, Ko teaches a releasable coupling (146).

Regarding claim 21, Ko teaches an adaptor (144).

Regarding claim 22, Jackson discloses wherein said fitting of said delivery tube assembly being configured for releasable connection to said supply unit (Figs. 1, 5, 6).

Regarding claim 23, Jackson discloses wherein said gas supply unit having a gas inlet (Fig. 1 below).

Regarding claim 24, Jackson discloses means for receiving gas from a source of gas and for delivering the gas to said gas inlet of said supply unit (Fig. 1).

Regarding claim 25, Jackson discloses a gas receiving means comprising a tube (Fig. 1).

Regarding claim 26, Jackson discloses said gas receiving means further comprising a fitting configured for connection to the source of gas (Fig. 1).

Regarding claim 27, Jackson discloses said supply unit having a liquid inlet configured to receive supplemental liquid (Fig. 1).

Regarding claims 32, 39, 42-45, note rejections of claims 16-18 and 20-27 above. The claimed method steps would have been obvious because they would have resulted from the use of the device of Jackson modified by Ko.

Regarding claim 34, Jackson discloses the claimed invention note rejection of claim 16 above. Jackson also discloses wherein the breathing gas is humidified by fluid (in 28) that has flowed through and reverses direction in the delivery tube (as the fluid flows back into tube 26, thereby reversing direction; Col. 2, lines 19-41).

Regarding claim 35, note rejection of claim 16 above.

Regarding claim 36, Jackson discloses wherein the fluid flow through the system is configured such that the fluid heats the breathing gas prior to humidifying the breathing gas (Fig. 1).

Regarding claims 37 and 38, note rejection of claim 16 above and the teaching by Ko of a nasal cannula.

Regarding claims 42-46, the claimed method steps would have been obvious because they would have resulted from the use of the device of Jackson/Ko rejected above with respect to claims 16-18 and 20-27.

**Claims 28-31, 33, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson ('795) in view of Ko ('527) as applied to claims 16-18 and 20-27 above, and further in view of McComb ('946) and Koch (6,367,472).**

Regarding claim 28, Jackson does not disclose a source of supplemental liquid coupled to said liquid inlet. Koch in a humidification device teaches a water fed via a line based upon static pressure providing a means to ensure the fibers are

surrounded by water on the outside (Col. 4, lines 58-62). It would have been obvious to one of ordinary skill in the art to provide a supplemental liquid coupled to the liquid inlet because it would have provided a means to ensure the fibers are surrounded by water on the outside as taught by Koch.

Regarding claim 29, Koch teaches a water supply bag (9, Col. 4, lines 58-62).

Regarding claim 30, Jackson/Ko discloses the claimed invention except for the supply unit being configured to delivery to deliver humidified gas at a flow rate of about 1 liter per minute to about 8 liters per minute.

McComb, in a system for delivering humidified gas to a patient, teaches a supply unit being configured to deliver humidified gas at flow rates between 3 to 150 liters/minute which includes a flow rate of about 1 liter per minute to about 8 liters per minute for the purpose of accommodating a patient's differing respiratory capacities and for accommodating a ventilator alone or a ventilator in combination with an anesthesia circuit (Col. 5, lines 48-61). It would have been obvious to modify the device of Jackson to provide a wide range of flow rates including 1-6 liters per minute because it would have provided a means for accommodating patient's having differing respiratory capacities and for accommodating a ventilator alone or a ventilator in combination with an anesthesia circuit as taught by McComb. Jackson also does not disclose the limitation of the relative humidity in a range of about 95% to about 100%. Koch in a humidifier device teaches relative humidity established a nearly constant humidification of the air fed in the range of 90% to 100% providing flow of gas, which is always humidified uniformly in continuous operation and in

intermittent operation (Col. 2, lines 21-33). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the flow rate at a relative humidity of 90% to 100% (which falls within the claimed parameters) because it would provide a flow of gas which is always humidified uniformly in continuous operation and in intermittent operation as taught by Koch.

Regarding claims 31 and 33 note rejection of claim 30 above.

Regarding claims 17 and 18, note rejection of claim 30 above.

### ***Response to Arguments***

Applicant's arguments filed 12/7/07 have been fully considered but they are not persuasive. Applicant argues that Jackson fails to disclose a supply unit configured to deliver humidified gas, a delivery tube assembly having a proximal end and a distal end, also applicant argues that Jackson does not disclose "means for" limitations of claim 39. Regarding the supply unit Jackson discloses a supply unit (which consist of 28, 24, 26, 18, 34) and is "configured for"; as for the limitations of the "mean for" as the elements of Jackson are an equivalent ((Jackson discloses a fluid supply at 28, a means for heating (as the water is heated to 100°F (Col. 2, lines 48-50) and a means for humidifying the breathing gas (18)). Also note rejections of claims above.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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Art Unit: 3771

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Art Unit 3771  
February 27, 2008

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